HEALTH AND SENIOR SERVICES
OFFICE OF MANAGED CARE

Managed Care Plans: Designation of Hemophilia Health Care Providers; Benefits or Coverage of Services for Hemophilia Treatment

Proposed New Rules: N.J.A.C. 8:38C-2 and 3

Authorized By: _____
Clifton R. Lacy, M.D., Commissioner
Department of Health and Senior Services

Authority: N.J.S.A. 26:2S-10.3.

Calendar Reference: See Summary below for explanation of exception to calendar requirements.

Proposal Number: PRN 2003-453

Submit comments by January 2, 2004 to:

Chanell McDevitt, Regulatory Officer
Office of Managed Care
Department of Health and Senior Services
P.O. Box 360
Trenton, NJ 08625-0360
Fax: (609) 633-0807

The agency proposal follows:

Summary

These proposed new rules are intended to implement the provisions of P.L. 2000, c. 121 (the Act), variously codified, but principally at N.J.S.A. 26:2S-10.1 through 10.3. The Act requires carriers to contract and/or refer covered persons solely to designated health care providers for the home treatment of hemophilia. The Act requires that the Department of Health and Senior Services (Department) designate the health care providers with which carriers may contract, or to which carriers may refer their covered persons for the purposes of obtaining services for the home treatment of bleeding episodes associated with hemophilia. The Act

establishes minimum standards that health care providers must meet in order to be designated as health care providers eligible to contract for the provision of home treatment of bleeding episodes associated with hemophilia.

These proposed new rules establish a process for health care providers to become designated to provide services for the home treatment of bleeding episodes associated with hemophilia, as well as a process for renewal or modification of the designation. In essence, the Department will accept applications for designation annually in September. Designations are valid for three years, so long as the designee continues to comply with the standards for designation. Designees are obligated to provide the Department with information regarding changes in their circumstances that may have an impact upon their designation status.

These proposed new rules also further define or establish additional standards for designation as a health care provider eligible to contract for the provision of home treatment of bleeding episodes associated with hemophilia. For example, the proposed new rules require that the applicant for designation have at least a special pharmacy permit, and be licensed as a health care provider pursuant to Title 45 or 26 of the New Jersey Statutes, registered as a health care service firm in accordance with N.J.A.C. 13:45B-14, or be contracted with an entity so licensed or registered, such that nursing services are readily available to clients when needed. In addition, the applicant for designation must be able to participate in, or respond to, Class I and Class II recalls issued by the federal government or drug and equipment manufacturers. Further, the applicant must demonstrate that it has at least a year of experience in the management of bleeding episodes, and at least one year of experience in the home treatment of bleeding episodes associated with hemophilia.

These proposed new rules establish standards for handling treatment when a health care provider loses designation, or the contract terminates between the carrier and the health care provider. In general, if a home treatment health care provider loses its designation because any of its licenses or permits are revoked, suspended, or surrendered, the health care provider must cease providing services for the home treatment of bleeding episodes associated with hemophilia immediately, except as may be necessary to coordinate transition of the covered person's care to another designated health care provider. When cessation of services occurs for other reasons, the health care provider is required to continue providing home treatment services and supplies for a specified period of time, or until another designated home treatment health care provider becomes available to the covered person.

These proposed new rules also interpret the Act's mandate that carriers provide benefits or coverage of services provided at clinical laboratories located in hospitals that are State-designated outpatient regional hemophilia care centers under certain circumstances, in order to clarify the statutory requirement. Among other things, these proposed new rules interpret the statutory reference to "State designated outpatient regional hemophilia care centers" to be the equivalent of the Federally-funded hemophilia treatment center network established through the United States Department of Health and Human Services. The Department has not attempted to establish a separate process for designating clinical laboratories for hospitals in New Jersey as outpatient regional hemophilia care centers, but has adopted the Federal standards instead. The Federally-funded hemophilia treatment center network is funded through the Maternal Child Health (MCH) Block Grant set-aside for Special Projects of Regional and National Significance (SPRANS), as a categorical funding component in accordance with the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, which amended Title V of the Social Security Act,

wherein the MCH Block Grant program is authorized. The participants in the Federally-funded hemophilia treatment center network are selected by the U.S. Department of Health and Human Services, and the networks are established on a regional basis, based on the ability and willingness of facilities to invest in the services to be delivered to the special population at issue, including outreach and education services. The Department did not think it practical to create a "State-designation" separate and apart from the Federal regional network, either in terms of use of Department resources, or incentives that facilities might have to seek a separate state designation. Afterall, no additional or alternative funding would be available to health care facilities on the basis of obtaining a separate State-designation, and coverage for expenses associated with use of a regional hemophilia treatment center is not contingent upon the regional hemophilia treatment center participating in a carrier's network when services at the regional hemophilia treatment center are prescribed by a physician and are medically necessary.

The Department has revised the statutory phraseology of "State-designated outpatient regional hemophilia care centers" to read as "State-recognized outpatient regional hemophilia care centers." This change in terminology is being proposed to serve as an indicator (albeit subtle) that the Department is not establishing a designation process for regional hemophilia care centers separate and apart from that already in existence at the Federal level. The change in terminology also is being proposed to help eliminate some confusion with the reference to "designated health care providers."

These proposed new rules specify that, when a carrier has a contract with a State-recognized outpatient regional hemophilia care center, the carrier may impose a requirement that the covered person use the contracted facility rather than another available State-recognized outpatient regional hemophilia care center in order for the covered person to avail themselves of

the full level of benefits or covered services under the terms of the health benefits plan. The proposed new rules also specify that, when the covered person goes outside of the carrier's network, and is covered under a health benefits plan that includes out-of-network benefits, then the covered person is entitled to the out-of-network benefits in accordance with the terms of the health benefits plan.

Pursuant to N.J.S.A. 26:2S-10.1(a), the Department developed the proposed rules in consultation with the Hemophilia Association of New Jersey (Hemophilia Association). These proposed new rules reflect the efforts of the Hemophilia Association as well as the Department's Division of Family Health Services and the Department's Office of Managed Care, Division of Health Care Systems Analysis.

A summary of the proposed new rules follows:

Proposed N.J.A.C. 8:38C-2.1 sets forth the purpose and scope of the rules relating to the designation of health care providers for purposes of contracting for the provision of services for the home treatment of bleeding episodes associated with hemophilia.

Proposed N.J.A.C. 8:38C-2.2 sets forth definitions for the subchapter.

Proposed N.J.A.C. 8:38C-2.3 iterates the carriers' obligation to only contract with or refer covered persons to designated home treatment health care providers.

Proposed N.J.A.C. 8:38C-2.4 sets forth the application procedures for becoming designated as a home treatment health care provider

Proposed N.J.A.C. 8:38C-2.5 establishes the qualifications that applicants for designation as a home treatment health care provider must demonstrate through the application.

Proposed N.J.A.C. 8:38C-2.6 provides a process for handling incomplete applications.

Proposed N.J.A.C. 8:38C-2.7 specifies that a determination that an application is complete does not bar the Department from requesting additional information based on the contents of an application.

Proposed N.J.A.C. 8:38C-2.8 sets forth the minimum standards the Department will use to review complete applications for designation as a home treatment health care provider.

Proposed N.J.A.C. 8:38C-2.9 provides for a renewal process for designation.

Proposed N.J.A.C. 8:38C-2.10 specifies the reasons for loss of designation, and when such a loss may be effective.

Proposed N.J.A.C. 8:38C-2.11 establishes standards for cessation of services by a health care provider following loss of designation or other reasons that may result in cessation.

Proposed N.J.A.C. 8:38C-2.12 sets forth the obligation of a designated health care provider to notify the Department of material changes in the health care provider's status.

Proposed N.J.A.C. 8:38C-2.13 sets forth the process for the Department to make the list of designees public.

Proposed N.J.A.C. 8:38C-2.14 addresses the interrelationship of the proposed new rules and Bulletin OMC 2001-04 (Bulletin). The Department issued the Bulletin in August of 2001 to provide carriers with an interim list of home treatment health care providers with whom it was acceptable for carriers to contract, or to whom covered persons could be referred within the spirit of the statute, and the list of facilities participating in the Federally-funded hemophilia treatment center network. The proposed new rules provide that use of these health care providers continues to be acceptable for a period of time following the effective date of the rules, but that eventually, the health care providers must file for designation in accordance with the requirements of the proposed rules; otherwise, carriers will no longer be able to continue

business with these health care providers with respect to the provision of home treatment of hemophilia.

The proposed Appendix to N.J.A.C. 8:38C-2 contains instructions and a checklist for submission of an application for designation as a hemophilia home treatment health care provider.

Proposed N.J.A.C. 8:38C-3.1 sets forth the scope and applicability of Subchapter 3, which addresses the obligations of carriers with respect to the provision of benefits or coverage of services for hemophilia treatment under managed care health benefits plans.

Proposed N.J.A.C. 8:38C-3.2 sets forth the definitions for the subchapter.

Proposed N.J.A.C. 8:38C-3.3 specifies the carrier's obligation to provide benefits or services for the home treatment of bleeding episodes associated with hemophilia. This proposed new rule is intended to make it clear that the preexisting statutory requirement to provide home treatment benefits (P.L. 1987, c. 63, effective March 10, 1987) is supplemented, not superceded, by the statutory requirement of P.L. 2000, c. 121. In addition, the proposed new rule establishes thresholds regarding how many designated hemophilia home treatment health care providers a carrier should have in its network.

Proposed N.J.A.C. 8:38C-3.4 deals with the situation in which a carrier's designated home treatment health care provider loses its designated status.

Proposed N.J.A.C.8:38C-3.5 addresses the termination of an agreement for services and supplies for home treatment of hemophilia.

Proposed N.J.A.C. 8:38C-3.6 discusses the Department's dissemination of information regarding designated home treatment health care providers, as well as State-recognized outpatient regional hemophilia care centers.

Proposed N.J.A.C. 8:38C-3.7 establishes standards regarding use of clinical laboratories at State-recognized outpatient regional hemophilia care centers.

Proposed N.J.A.C. 8:38C-3.8 addresses the interrelationship the proposed new rules and the Bulletin issued by the Department (see the previous discussion above).

Proposed N.J.A.C. 8:38C-3.9 requires carriers to provide notice to the Department within 60 days following the effective date of the rules of the persons with which the carriers have contracted for the provision of home treatment of bleeding episodes associated with hemophilia.

Proposed N.J.A.C. 8:38C-3.10 addresses the issue of violations of the subchapter by carriers.

A 60-day comment period is provided for this proposal; thus, in accordance with N.J.A.C. 1:30-3.3(a), this proposal is not subject to the provisions of N.J.A.C. 1:30-3.1 and 3.2 governing rulemaking calendars.

Social Impact

The Department believes that the purpose of the Act was to assure that covered persons with hemophilia have access within managed care networks to high caliber, qualified health care providers with specific expertise in treating bleeding episodes associated with hemophilia. These proposed new rules are intended to implement the provisions of the Act.

The Department anticipates the social impact will be positive. Assuring access to highly qualified and specialized health care providers for a particularly vulnerable population cannot be anything but positive for all concerned. Quick and appropriate treatments help to reduce time lost from both school and work, and result in better health care outcomes generally. This, in

turn, can be expected to increased productivity and quality of life for affected individuals and their families.

Economic Impact

The economic impact is unclear. There will be some adverse economic impact for health care providers. Those that have been providing home treatments for hemophilia bleeding episodes under contract or other arrangement with carriers that elect not to seek designation will no longer be able to provide those services to the carrier's population, and thus, may see some reduction in their revenue. However, because the affected population is quite small, it is unlikely that most health care providers offering home care services will incur significant impact from the loss of this particular business. Those health care providers that elect to become designated will incur some costs related to the submission and review of their applications, and subsequent renewals. Depending upon their current status, the costs they incur to become designated may be nominal (for example, they may only need to put together the paperwork demonstrating their qualifications), or more substantial if they are just starting-up in New Jersey, and believe this is a service niche that they can fill. However, the added revenues that designated home treatment health care providers may receive from being in such a selective class of health care providers may off-set some of the regulatory costs that will be incurred.

Carriers may incur some expenses related to these proposed new rules if they have not previously contracted with home treatment health care providers that are likely to become designated. They will no longer be able to refer their covered persons in need of home treatment for bleeding episodes associated with hemophilia to non-designated home treatment health care providers, but will need to either add a designated home treatment health care provider to their

network, or make other arrangements to assure that their covered persons can access services from such a health care provider at full benefits or coverage of services. This may result in increased administrative costs, and possibly, in increased claims costs as well for home treatment services. Carriers are likely to incur some increased costs related to use of clinical laboratories at hospitals with State-recognized outpatient regional hemophilia care centers. However, the extent to which the carrier may incur increased costs will depend upon the carrier's current operations, contracts, protocols and practices, as well as the carrier's number of covered persons utilizing these services. The increased costs are unlikely to be large for any carrier.

Because use of these specialized services are likely to result in better health outcomes generally, the costs associated with other treatments for hemophilia (notably, inpatient expenses) may decline. These decreases may off-set any increases that may result in other claims and administrative costs.

In general, the Department does not expect these proposed rules to have a significant economic impact upon the costs of insurance products or premiums for purchasers. Further, while the Department acknowledges that some parties may elect to utilize consultants or other outside resources in addressing the requirements of the proposed rules, the Department does not believe that compliance necessitates such expenditures. The statutes required promulgation of regulations to establish a designation system, narrowing the field of possible health care providers eligible to contract with carriers, and increasing the potential utilization of out-of-network providers; costs associated with these statutory requirements are unavoidable.

Federal Standards Statement

A Federal standards analysis is not required because the Department's proposed new rules do not address any matter that is the subject of Federal regulation.

Jobs Impact

The Department does not anticipate any generation or loss of jobs as the result of the proposed new rules.

Agriculture Industry Impact

Pursuant to N.J.S.A. 4:1C-10.3, the Right to Farm Act, and N.J.S.A. 52:14B-4(a)(2) of the Administrative Procedure Act, the Department does not expect the proposed new rules to have any impact upon the agriculture industry.

Regulatory Flexibility Analysis

These proposed new rules do not impose any requirements that necessitate professional services. These proposed new rules do impose new recordkeeping or reporting requirements, in that health care providers seeking to become designated must file an application for consideration, and renewal applications to maintain a designation. In addition, designated home treatment health care providers will be under an obligation to notify the Department of material changes in their status. Further, these proposed new rules may have an impact upon one or more businesses resident in New Jersey that employ 100 or fewer employees, and which are not

dominant in their industry, and thus, are "small businesses" as defined by N.J.S.A. 52:14B-16 et seq.

Notwithstanding the impact that these proposed new rules may have upon business, and small business in particular, these proposed new rules do not provide any regulatory flexibility for purposes of compliance. The Act did not indicate that any such flexibility should be permitted. Further, the Department does not believe it is reasonable to reduce any of the requirements based on the size of the business. These proposed new rules seek to protect the health and welfare of a particularly vulnerable population, and the interests and needs of this population should not be compromised based on the size of a company interested in providing health care services. Accordingly, no accommodation for entities that may be small businesses has been made.

Smart Growth Impact

The proposed new rules will have no impact on the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follows:

CHAPTER 38C

MANAGED CARE PLANS

SUBCHAPTER 1 (RESERVED)

SUBCHAPTER 2. DESIGNATION OF HEMOPHILIA HEALTH CARE PROVIDERS

8:38C-2.1 Scope and applicability

(a) This subchapter shall apply to all carriers offering health benefits plans that are managed care plans, and to all such health benefits plans offered by a carrier.

(b) This subchapter shall apply to all persons desiring to contract with carriers for the provision of home treatment services for bleeding episodes associated with hemophilia.

8:38C-2.2 Definitions

For the purposes of this subchapter, the words and terms set forth below shall have to following meanings, unless the context clearly indicates otherwise.

"Blood infusion equipment" means at least syringes and needles.

"Blood product" means products that include, but are not limited to, Factor VII, Factor VIII, and Factor IX .

"Carrier" means an insurance company authorized to transact the business of insurance in this State and doing a health insurance business in accordance with N.J.S.A. 17B:17-1 et seq., a hospital service corporation authorized to do business pursuant to N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to do business pursuant to N.J.S.A. 17:48A-1 et seq., a health service corporation authorized to do business pursuant to N.J.S.A. 17:48E-1 et seq., or a health maintenance organization authorized to do business pursuant to N.J.S.A. 26:2J-1 et seq.

"Covered person" means the natural person on whose behalf a carrier is obligated to pay benefits or provide health care services pursuant to the health benefits plan.

"Department" means the New Jersey Department of Health and Senior Services.

"Designation" or "designated" means that a health care provider has been approved by the Department to contract with carriers for the purpose of rendering services for the home treatment of bleeding episodes associated with hemophilia.

"Health benefits plan" means a policy or contract for the payment of benefits for hospital and medical expenses or the provision of hospital and medical services, that is delivered or issued for delivery in this state by a carrier. The term "health benefits plan" specifically includes:

1. Medicare supplement coverage and risk contracts for the provision of health care services covered by Medicare to the extent that state regulation of such contracts or policies is not otherwise preempted by Federal law; and

2. Any other policy or contract not otherwise specifically excluded by statute or this definition.

The term "health benefits plan" specifically excludes:

1. Accident only policies;

2. Credit health policies;

3. Disability income policies;

4. Long-term care policies;

5. TRICARE/CHAMPUS coverage, or supplements thereto;

6. Hospital confinement indemnity coverage;

7. Coverage arising out of a workers' compensation law or similar such law;

8. Automobile medical payment insurance or personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq.; and

9. Coverage for medical expenses contained in a liability insurance policy.

"Health care practitioner" means a natural person licensed pursuant to Title 45 of the New Jersey Statutes.

"Health care provider" means a health care practitioner or other person licensed to deliver one or more health care services pursuant to Title 45 or Title 26 of the New Jersey Statutes, or a health care service firm .

"Health care service firm" means health care service firm as that term is defined at N.J.A.C. 13:45B-14.2.

"Managed care plan" means a health benefits plan that integrates the financing and delivery of appropriate health care services to covered persons by agreement with participating health care providers, who are selected to participate on the basis of explicit standards, to furnish a comprehensive set of heath care services and financial incentives for covered persons to use the participating health care providers and procedures set forth in the plan.

"Person" means both natural and legal person, except as otherwise specified.

8:38C-2.3 Carriers responsibility to use designated health care providers for home treatments

(a) No carrier shall arrange with any person for the provision of home treatment of bleeding episodes associated with hemophilia unless that person shall be a designated health care provider of such services.

(b) Carriers with an aggregate enrollment of 50,000 covered persons or more in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least two designated health care providers, unless there are fewer than two designated health care providers designated in New Jersey, in which event, the

carrier shall arrange for the provision of home treatment services with the lone designated health care provider, regardless of the carrier's enrollment.

(c) Carriers with aggregate enrollment of fewer than 50,000 covered persons in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least one designated health care provider.

(d) Nothing in this subchapter shall be construed to limit or eliminate any carrier's obligation to credential and re-credential health care providers with which the carrier arranges for the provision of home treatment of hemophilia with respect to such treatments or any other services that the health care provider may render to a carrier's covered persons.

8:38C-2.4 Application: procedure to become a designated health care provider of home treatment services

(a) A person seeking to become a designated health care provider shall submit an application to the Department within 60 days following (the effective date of these proposed new rules), or during the month of September in each calendar year thereafter.

(b) A person seeking to become a designated health care provider shall submit an original and at least one copy of the application to the Department in accordance with (a) above to:

Attn: Hemophilia Treatment Designation Application
Office of Managed Care
NJ Department of Health and Senior Services
Market & Warren Streets
P.O. Box 360

Trenton, NJ 08625-0360

(c) The applicant shall comply with "Instructions and Checklist" set forth in the Appendix to this subchapter, incorporated herein by reference, when submitting the application, in addition to the following:

1. The application shall include notarized copies of all current registrations, licenses and permits held by the applicant that have been issued by a New Jersey regulatory agency; and

2. The application shall include a certification signed by an officer of the applicant company, which shall include:

i. A statement that the information contained in the application is accurate and true to the knowledge of the signatory;

ii. A statement that the signatory is authorized to make the certification and submit legal documents on behalf of the applicant company; and

iii. The signatory's printed title, printed name, and the printed date the certification was signed.

(d) Applicants may submit copies of the application in paper or electronic format, or both, subject to the requirement that at least one copy of the application be in paper format, and that the original and copy(ies) be set forth in the same order and contain the same content.

(e) The applicant shall submit a response to each of the requirements set forth in N.J.A.C. 8:38C-2.5.

8:38C-2.5 Application: demonstration of qualifications for becoming a designated health care provider of home treatment services

(a) The applicant shall submit notarized copies of all registrations, licenses and permits issued to the applicant by the State of New Jersey pursuant to Title 45 and Title 26 of the New Jersey Statutes, and shall demonstrate that the applicant is in good-standing with respect to such licenses, registrations and permits.

(b) The applicant shall demonstrate each of the following:

1. Its ability to provide services and to maintain and provide all brands of blood product, including low, medium and high-assay range levels to execute treatment regimens as prescribed by a covered person's attending physician, without making substitutions of blood products except upon prior approval of the attending physician;

2. Its ability to maintain and provide all needed ancillary supplies for the treatment or prevention of bleeding episodes, including blood infusion equipment and cold compression packs;

3. Its ability to deliver any and all prescribed blood products, medications, nursing services and blood infusion equipment within three hours after receipt of a prescription for a covered person's emergent situation, 24-hours per day, seven days per week;

4. Its experience in management of bleeding disorders.

i. Experience may be demonstrated by performance of services in other states.

ii. Experience shall include, at a minimum, the provision of services for the home treatment of hemophilia;

5. Its ability to perform appropriate record-keeping and maintain appropriate records, consistent with the medical and health record standards for home health agencies at N.J.A.C. 8:42;

6. Its ability to monitor and actively participate in product recall and notification systems, both drug-related and otherwise;

7. Its ability to assist covered persons in obtaining third party reimbursements when necessary or appropriate;

8. Its ability to comply with proper removal and disposal of hazardous waste, in accordance with the standards applicable to home health agencies at N.J.A.C. 8:42;

9. That it has written policies and procedures regarding the discontinuation of services when an individual is no longer able to pay for or assure payment of the costs associated with the services rendered by the applicant.

i. The applicant shall submit its written policies and procedures to the Department.

ii. The applicant's written policies and procedures shall address the issue of dissemination of the policies and procedures to covered persons upon request;

10. Its ability to disseminate information to covered persons regarding probable costs for services that the applicant may provide that are not covered by a covered person's health benefits plan; and

11. Its program for credentialing and recredentialing the health care practitioners or other health care providers contracted with or employed by the applicant.

8:38C-2.6 Application: process for incomplete applications

(a) The Department shall review applications to determine whether they are complete.

(b) If the Department determines that an application is incomplete, the Department shall provide a written notice to the applicant of this determination with an explanation of why the application is incomplete, and shall return all documentation and electronic files submitted with the incomplete applications to the applicant.

(c) Within 45 days after the Department sends notice to the applicant that the application is incomplete, an applicant may resubmit the application with the information necessary to make the application complete. The Department shall not consider perfected applications outside of the specified 45-day timeframe, nor shall the Department retain the perfected application.

1. The Department shall return the application to the applicant only if the resubmitted application includes prepaid return mail packaging.

8:38C-2.7 Application: complete applications and additional information

(a) The Department may request additional information from the applicant notwithstanding a determination that the application is complete, if the Department believes such information is relevant to the Department's review of the application.

(b) The Department may consider additional information received from the applicant or from other sources if the Department believes the information is relevant to the Department's review of the application, notwithstanding a determination that the application is complete.

8:38C-2.8 Department review: minimum standards for designation

(a) An applicant shall possess a pharmacy permit issued by the New Jersey Board of Pharmacy pursuant to N.J.A.C. 13:39-4, which may be a specialized permit issued in accordance with N.J.A.C. 13:39-4.16.

1. With respect to the applicant's pharmacy permit, at least some portion of the applicant's pharmacy services shall be dedicated to the provision of services and supplies specifically for the treatment of hemophilia.

(b) If the applicant's blood products include cryoprecipitate, the applicant shall possess a blood bank license issued by the Department in accordance with N.J.S.A. 26:2A-2 et seq., and rules promulgated pursuant thereto, specifically N.J.A.C. 8:8.

(c) An applicant shall be either a health care service firm registered with the New Jersey Department of Law and Public Safety, Division of Consumer Affairs, in accordance with N.J.A.C. 13:45B-14, or a health care provider licensed pursuant to N.J.S.A. 26:2H-1 et seq., or the applicant shall have a contract with one or more other persons having such a registration or license that has the ability to assure the provision of in-home nursing services when needed by a covered person.

(d) The applicant shall be in good-standing with respect to all of its registrations, licenses and permits, as shall be the pharmacists employed by or contracted with the applicant, and other persons, if any, contracted with the applicant in accordance with (c) above.

(e) The applicant shall demonstrate to the Department's satisfaction that the applicant meets the requirements of N.J.A.C. 8:38C-2.5(b), including, but not limited to, the following:

1. The applicant shall demonstrate that it has at least one year of experience in the management of bleeding episodes, with at least one year of experience with home

treatment of bleeding episodes associated with hemophilia, addressing the needs of at least 10 individuals diagnosed with hemophilia;

2. The applicant shall demonstrate its ability to actively participate in both Class I and Class II drug recalls, both in terms of receiving or obtaining information from multiple sources and disseminating information to clients, including covered persons to whom services have been rendered;

3. The applicant shall have a policy of accepting assignment of benefits when the applicant is not under contract with a carrier or other payer and assignment of benefits is an available option;

4. The applicant shall have knowledge and experience in third party billing of carriers, Medicare, Medicaid and other payers, and in obtaining successful reimbursement.

i. The applicant may rely upon the demonstrated experience of a billing agent under contract with the applicant.

ii. The applicant's knowledge and experience shall include coordination of benefits between and among government programs and other forms of health benefits plans and self-funded agreements;

5. The applicant shall have a policy against presentation of any bill to or the collection of any monies from a covered person of a carrier with which the applicant has an agreement for the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as may be appropriate to collect the copayments, deductibles or coinsurance amounts the covered person is required to pay under the terms of his or her health benefits plan(s), and the applicant shall agree not to hold such a covered person liable for any monies (other than copayments, deductibles or coinsurance amounts) for which the carrier is

responsible pursuant to the terms of the covered person's health benefits plan(s) and the agreement between the carrier and the applicant, regardless of whether the applicant believes the carrier has fulfilled its obligations;

6. At a minimum, the applicant's written policy regarding discontinuation of services shall specify that:

i. The applicant shall continue to provide services and supplies to an individual, notwithstanding that the individual ceases to be able to assure payment for some or all of the costs of services and supplies, until the individual obtains an alternate source of services and supplies, up to at least four months after the occurrence of one of the following: loss of coverage under a health benefits plan; ineligibility for benefits or exhaustion of benefits under a health benefits plan; a requirement to satisfy deductibles, coinsurance, co-payments or other cost-sharing requirements or liability for excess costs or excluded items of expense;

ii. The applicant shall continue to provide services and supplies to an individual in the event the applicant and the covered person's carrier terminate the agreement which includes among its terms, the provision of services and supplies to a covered person for home treatment of bleeding episodes associated with hemophilia, for at least four months, or until the individual obtains an alternate source of services and supplies, whichever occurs first, except when termination is the result of the health care provider losing designation as a home treatment health care provider, or for breach, fraud or a determination by the carrier's medical director that the health care provider is an imminent danger to one or more covered persons, whether such breach, fraud or imminent harm is related to the provision of services or supplies for home treatment of bleeding episodes associated with hemophilia, or other services and supplies for which the carrier and health care provider have an agreement;

iii. The applicant shall refer the individual to the Hemophilia Association of New Jersey to obtain help and information about resources as soon as possible following the occurrence of the situations described in (e)6i or 6ii above; and

iv. The applicant shall provide the policies and procedures to a covered person in writing prior to the applicant's initial provision of services to the covered person, and to covered persons and carriers upon request; and

7. The applicant's staff credentialing program shall require primary source verification of licenses and permits, and shall require recredentialing at least every three years.

(d) If, in the Department's opinion, the applicant does not meet the standards for designation, the Department shall provide a written notice of that determination, with an explanation therefor, to the applicant.

1. An applicant may appeal the Department's determination, and request a hearing in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, but shall not be entitled to enter into any agreement with a carrier for the provision of home treatment for bleeding episodes associated with hemophilia until and unless a final decision in favor of the applicant has been obtained.

2. An applicant shall have the right to make a new application consistent with the requirements of N.J.A.C. 8:38C-2.4 without regard to whether the applicant has requested a hearing and the request has been granted.

(e) If, in the Department's opinion, an applicant meets the standards for designation, the Department shall provide written notice to the applicant, confirming the applicant's designation.

8:38C-2.9 Renewal of designation as a health care provider of home treatment of bleeding episodes associated with hemophilia

(a) Designation as a health care provider for home treatments of bleeding episodes associated with hemophilia shall be effective until the end of the third September following the date of the health care provider's most recent designation, unless there is a change in the status of the designated health care provider that makes the health care provider ineligible for the designation at an earlier date.

(b) In order to avoid loss of designation, a designated health care provider shall submit an application to maintain its designation at least 30 days prior to the date on which its designation is scheduled to expire.

(c) A designated health care provider shall comply with the requirements of N.J.A.C. 8:38C-2.4 and 2.5, or its renewal application shall be considered incomplete.

(d) The Department shall apply the same standards to renewal applications for designation as it applies to initial applications for designation.

(e) In the event that a designation expires due to inaction or late action by the designated health care provider or any of its agents, the health care provider shall not have a right to request a hearing on the loss of the designation, and the health care provider and carrier shall end their relationship regarding the provision of services and supplies for the home treatment of hemophilia in accordance with N.J.A.C. 8:38C-2.10.

8:38C-2.10 Loss of designation as a home treatment provider

(a) A designated health care provider may lose its designation as the result of one or more of the following:

1. Revocation, suspension or surrender of a registration with respect to a health care service firm;

2. Revocation, suspension or surrender of a license with respect to health care providers;

3. Revocation, suspension or surrender of a pharmacy permit, including a specialized permit, unless the specialized permit was surrendered in order to be replaced by another form of pharmacy permit;

4. Failure of the health care provider to meet one of the standards on which designation was originally issued, other than maintenance by the health care provider and/or its subcontractors of registration(s), license(s) or permit(s) in good standing;

5. Failure of the health care provider to submit a timely request for renewal of its designation; or

6. Failure of a designated health care provider to report material changes in accordance with N.J.A.C. 8:38C-2.12.

(b) With respect to a revocation, suspension or surrender of a registration, license or permit, as set forth in (a)1, 2 and 3 above, loss of the health care provider's designation shall be immediate upon occurrence of the event, and shall not be contingent upon notification, verbal or written, being sent from the Department.

(c) When a designated health care provider has failed to timely submit an application to renew its designation, and the loss of designation results solely on that basis, the loss of designation shall be effective as of October 1 in the designation renewal year for that health care

provider, and shall not be contingent upon notification, verbal or written, being sent from the Department to the health care provider.

(d) Except as (b) and (c) above applies, loss of designation shall be effective upon the date that written notice of the loss of designation is sent by the Department to the designated health care provider.

(e) In the event that a designated health care provider loses its designation, the health care provider shall be entitled to request a hearing regarding the loss of the designation in accordance with the provisions of the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, except when loss of the designation results from (a) 1, 2 or 3 above.

(f) Upon receipt of notice of loss of its designation, a health care provider shall notify all of the carriers with which it has an agreement to provide home treatment for bleeding episodes associated with hemophilia of the loss of the designation, and all of the covered persons to whom such services have been or currently are being rendered, and shall cease offering home treatment services, at a minimum, in accordance with N.J.A.C. 8:38C-2.11.

1. Verbal notification shall be acceptable for purposes of expediency; however, the health care provider shall send written notification of the loss of designation to carriers and covered persons.

(g) No health care provider shall advertise or otherwise hold itself out to any carrier, covered person or any other person as a designated health care provider in any medium following the loss of designation.

8:38C-2.11 Cessation of services

(a) When loss of designation results from a situation set forth at N.J.A.C. 8:38C-2.10(a)1, 2 or 3, the health care provider shall cease providing home treatment for bleeding episodes associated with hemophilia immediately.

1. The health care provider shall coordinate with the carrier to arrange for another designated health care provider, whether or not in the carrier's network, to provide services to covered persons, prior to withdrawal of any nursing services or supplies from the home of any covered person.

(b) When the loss of designation results for any other reason not specified in N.J.A.C. 8:38C-2.10(a)1, 2 or 3, the health care provider shall continue to provide services and supplies to covered persons that have been receiving services and supplies from the health care provider, at the option of the covered person, for four months following the loss of designation, or until the covered person is able to obtain services and supplies from another designated health care provider, whichever occurs first, but shall not provide services to any other covered person for the home treatment of bleeding episodes associated with hemophilia.

1. The health care provider shall coordinate with the carrier to arrange for another designated health care provider, whether or not in the carrier's network at that time, to provide services to covered persons.

(c) A health care provider that continues to provide services for home treatment of bleeding episodes associated with hemophilia following loss of its designation shall continue to abide by all aspects of its agreement with the carrier for the provision of such services, except those that would otherwise cause it to be in violation of this section.

(d) A health care provider shall comply with the requirements of (a) or (b) above, as appropriate to the health care provider's situation, notwithstanding that the health care provider may have requested, and the Department may have granted the request, for a hearing.

8:38C-2.12 Obligation of designated health care provider to notify Department of material changes

(a) Every designated health care provider shall have an affirmative obligation to provide notice to the Department about any material change in the information provided to the Department on which the health care provider's designation was based.

1. Health care providers shall report changes in writing at least 30 days prior to the expected date of change, or within no more than 10 days following the date of a change that was unexpected.

2. In providing notice of a change, expected or unexpected, a health care provider shall specify what action it plans to take to assure that it remains in compliance or comes back into compliance with the standards for designation.

i. With respect to providing information regarding a plan to bring the health care provider back into compliance with the standards for designation, the plan shall be structured to assure that the health care provider is in compliance within no more than 45 days following the material change.

3. If the plan of correction is acceptable and implemented, no loss of designation will occur, except when the material change is revocation or surrender of a license, permit or registration, or a suspension that cannot be remedied in 45 days.

(b) Failure of a designated health care provider to submit a notice of material change to the Department shall be grounds for the Department to revoke the health care provider's designation.

8:38C-2.13 Designation list

(a) The Department shall maintain a written list of designated home treatment health care providers, which shall be made available to any person upon request made to the Department, and shall be maintained on the Department's Internet site.

(b) The list for general distribution, whether in paper or electronic format, shall be updated as frequently as necessary, but shall be published as a public notice in the New Jersey Register no more frequently than annually.

8:38C-2.14 Effect of Bulletin OMC 2001-04

(a) Those persons identified in Bulletin OMC 2001-04 as acceptable providers of services for home treatment of bleeding episodes associated with hemophilia for purposes of carriers making agreements and fulfilling their obligations pursuant to N.J.S.A. 26:2S-10.1 prior to adoption of this subchapter, shall continue to be considered acceptable until the 61st day following (the effective date of these proposed new rules), except as (b) below applies.

(b) A person identified in Bulletin OMC 2001-04 as an acceptable provider of services for home treatment of bleeding episodes associated with hemophilia that submits an application for designation within 60 days following (the effective date of these proposed new rules) shall continue to be considered acceptable for purposes of carriers making agreements to

fulfill their obligations pursuant to N.J.S.A. 26:2S-10.1 until such time as it is determined that the person does not meet the requirements for designation.

(c) A person identified in Bulletin OMC 2001-04 as an acceptable provider of services for home treatment of bleeding episodes associated with hemophilia shall comply with 8:38C-2.10 and 2.11 if the person:

1. Elects not to submit an application for designation;

2. Submits an application that is determined incomplete and does not resubmit the application; or

3. Submits a complete application but receives notice that it will be not be designated by the Department.

(d) A carrier that has an agreement with a person identified as an acceptable provider of services for home treatment of bleeding episodes associated with hemophilia that does not become designated shall comply with N.J.A.C. 8:38C-3.8.

APPENDIX

APPLICATION FOR DESIGNATION AS A HEMOPHILIA HOME TREATMENT HEALTH CARE PROVIDER – INSTRUCTIONS AND CHECKLISTS

INSTRUCTIONS: New and renewal applications should be submitted in September each year; applications submitted at other times will not be considered.* Applications must be complete. If a question or requirement does not apply to an applicant's particular circumstances, the applicant must so indicate that, rather than ignoring the question or requirement.

PART A: Form

The following checklist is provided to help applicants complete their applications properly. However, completion of the checklist shall not result in an application being deemed complete or approved. Applicants shall refer to N.J.A.C. 8:38C-2 for details.

- ☐ The application is being submitted in duplicate.
- ☐ At least one copy of the application is being submitted in paper format
- ☐ The paper copy is being submitted in one or more two- or three-ring binders
- ☐ Binders are labeled to indicate the number of binders included in the submission
- ☐ Disks, if any, are labeled to indicate the number of disks included in the submission
- ☐ The application is being sent to:

Attn: Hemophilia Treatment Designation Application
Office of Managed Care
NJ Department of Health and Senior Services
P.O. Box 360
Trenton, NJ 08625-0360
(if by other than U.S. Postal, Market & Warren Streets substitutes for P.O. Box 360)

- ☐ All copies of registrations, licenses and permits are notarized
- ☐ The application includes a certification signed by an officer of the applicant company
- ☐ The officer's name and title is printed in the certification
- ☐ The application contains a Table of Contents
- ☐ The application is tabbed consistent with the Table of Contents
- ☐ The pages of the application are numbered, and pages intentionally left blank are so indicated

Part B: Content

The following checklist is provided to help applicants complete their applications properly. However, completion of the checklist shall not result in an application being deemed complete or approved. Applicants shall refer to N.J.A.C. 8:38C-2 for details.

- ☐ Notarized copies of all registrations, licenses and permits issued to the applicant by the State of New Jersey pursuant to Titles 45 and 26 of the New Jersey statutes or N.J.A.C. 13:45B-14 are enclosed.
- ☐ The application includes evidence of the applicant's ability to provide all blood products, including low, medium and high-assay levels
- ☐ The application includes evidence of the applicant's ability to provide all needed ancillary supplies for the treatment of bleeding episodes, including blood infusion equipment and cold compression packs

- ☐ The application includes evidence of the applicant's ability to deliver prescribed services and supplies within 3-hours after receipt of a prescription, 24 hours per day, year-round
- ☐ The application includes evidence of the applicant's experience in management of bleeding disorders
- ☐ The application includes evidence of the applicant's ability to perform appropriate record-keeping and to maintain appropriate records
- ☐ The application includes evidence of the applicant's ability to monitor and participate in product recall notification systems
- ☐ The application includes evidence of the applicant's willingness to assist, and experience in assisting, individual clients in addressing third party reimbursement issues
- ☐ The application includes evidence of the applicant's compliance with safe handling standards with respect to biological products, including removal and disposal of hazardous waste products
- ☐ The application includes evidence of the applicant's policies and procedures regarding discontinuation of services and supplies when individual clients are no longer able to assure payment for services and supplies, and willingness to share these policies and procedures with individual clients and carriers
- ☐ The application includes evidence of the applicant's ability and willingness to disseminate information to individual clients regarding the applicant's schedule(s) of costs, including projections of probable costs to individual clients based on an individual client's health benefits plan(s).
- ☐ The application includes evidence of the applicant's credentialing and recredentialing program for health care practitioners and other health care providers employed by or with which the applicant contracts for services and supplies.

*Applications will be accepted initially within 60 days following (the effective date of N.J.A.C. 8:38C-2).

SUBCHAPTER 3. BENEFITS OR COVERAGE OF SERVICE FOR HEMOPHILIA TREATMENT

8:38C-3.1 Scope and applicability

(a) This subchapter shall apply to all carriers offering health benefits plans that are managed care plans, and to all such health benefits plans offered by a carrier.

(b) This subchapter applies only with respect to the provision of services for treatment of hemophilia, and do not have a direct bearing on the relationship between a carrier and a health care provider for the provision of any other services or supplies.

(c) Nothing in this subchapter shall be construed to limit the obligation of any carrier to comply with other laws regarding the provision of benefits or services for the treatment of hemophilia.

8:38C-3.2 Definitions

For the purposes of this subchapter, the words and terms set forth below shall have the following meanings, unless the context clearly indicates otherwise.

"Carrier" means an insurance company authorized to transact the business of insurance in this State and doing a health insurance business in accordance with N.J.S.A. 17B:17-1 et seq., a hospital service corporation authorized to do business pursuant to N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to do business pursuant to N.J.S.A. 17:48A-1 et seq., a health service corporation authorized to do business pursuant to N.J.S.A. 17:48E-1 et seq., or a health maintenance organization authorized to do business pursuant to N.J.S.A. 26:2J-1 et seq.

"Covered person" means the natural person on whose behalf a carrier is obligated to pay benefits or provide health care services pursuant to the health benefits plan.

"Department" means the New Jersey Department of Health and Senior Services.

"Designation" or "designated" means that a health care provider has been approved by the Department to contract with carriers for the purposes of rendering service for the home treatment of bleeding episodes associated with hemophilia.

"Health benefits plan" means a policy or contract for the payment of benefits for hospital and medical expenses or the provision of hospital and medical services, that is delivered or issued for delivery in this state by a carrier. The term "health benefits plan" specifically includes:

1. Medicare supplement coverage and risk contracts for the provision of health care services covered by Medicare to the extent that state regulation of such contracts or policies is not otherwise preempted by Federal law; and

2. Any other policy or contract not otherwise specifically excluded by statute or this definition.

The term "health benefits plan" specifically excludes:

1. Accident only policies;

2. Credit health policies;

3. Disability income policies;

4. Long-term care policies;

5. TRICARE/CHAMPUS coverage, and supplements thereto;

6. Hospital confinement indemnity coverage;

7. Coverage arising out of a workers' compensation law or similar such law;

8. Automobile medical payment insurance or personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq.; and

9. Coverage for medical expenses contained in a liability insurance policy.

"Health care provider" means a person licensed to deliver one or more health care services pursuant to Title 45 or Title 26 of the New Jersey Statutes, or a health care service firm as that term is defined at N.J.A.C. 13:45B-14.2.

"Managed care plan" means a health benefits plan that integrates the financing and delivery of appropriate health care services to covered persons by agreement with participating health care providers, who are selected to participate on the basis of explicit standards, to furnish a comprehensive set of heath care services and financial incentives for covered persons to use the participating health care providers and procedures set forth in the plan.

"Person" means both legal and natural person except as otherwise specified.

"State-recognized outpatient regional hemophilia care center" means a health care facility participating in the Federally-funded hemophilia treatment center network, as determined by the United States Department of Health and Human Services, that is located within New Jersey's geographic borders, without regard to the hemophilia treatment center's Federally-designated region.

8:38C-3.3 Carrier's obligation to provide benefits or services for the home treatment of bleeding episodes associated with hemophilia

(a) Every carrier shall provide for, in its managed care plans, in-network benefits or services for the home treatment of bleeding episodes associated with hemophilia.

(b) No carrier shall arrange with any person for the provision of home treatment of bleeding episodes associated with hemophilia unless that person shall be a designated provider of such services, nor shall a carrier refer any covered person to a person that is not a designated health care provider of services and supplies for the home treatment of bleeding episodes associated with hemophilia.

(c) Carriers with an aggregate enrollment of 50,000 covered persons or more in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least two designated health care providers, unless there are fewer than two designated health care providers designated in New Jersey, in which event, the carrier shall arrange for the provision of home treatment services with the lone designated health care provider, regardless of the carrier's enrollment.

(d) Carriers with aggregate enrollment of fewer than 50,000 covered persons in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least one designated health care provider.

(e) Nothing in this subchapter shall be construed to limit the obligation of a carrier to provide out-of-network benefits for home treatment services accessed at the option of the covered person through a health care provider that is not designated, when the managed care plan has an out-of-network benefits component.

(f) Nothing in this subchapter shall be construed to limit the obligation of a carrier to provide benefits or services on an in-network basis when a covered person accesses home treatment services from a health care provider, designated or not, because the carrier fails to have an agreement with a designated health care provider to provide services for the home treatment

of bleeding episodes associated with hemophilia to the covered person at the time that such services are prescribed.

8:38C-3.4 Loss of designated status

(a) When a designated health care provider with which the carrier has arranged for the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia loses designation, the carrier shall not continue to refer covered persons to the services and supplies of that health care provider for home treatment of bleeding episodes associated with hemophilia.

(b) With respect to covered persons that have been receiving services and supplies from a health care provider that has lost its designation, the carrier shall continue to provide services or benefits to or on behalf of the covered person at an in-network level for home treatment services and supplies, until such time as arrangements are made for the covered person to receive home treatment services and supplies from another in-network designated health care provider, or for four months following the date of the loss of designation, whichever occurs first.

1. Notwithstanding (b) above, the carrier shall not be required to continue to provide services or benefits to a covered person at an in-network level when the health care provider's loss of designation is the result of revocation or surrender of a license, permit or registration, or is the result of a suspension of a license, permit or registration that cannot be corrected by reinstatement within 45 days following the date of the suspension, except as may be necessary for the carrier and health care provider to transition the covered person's care to another designated health care provider, consistent with N.J.A.C. 8:38C-2.11(a).

(c) Nothing in this subchapter shall be construed to necessarily require termination of the agreement between the carrier and health care provider, or otherwise affect the agreement to the extent that it addresses the provision of services or supplies to covered persons by the health care provider, or the performance of other functions under the terms of the agreement, separate from those related to the home treatment of bleeding episodes associated with hemophilia.

8:38C-3.5 Termination of the agreement for services and supplies for home treatment of bleeding episodes associated with hemophilia

(a) In the event that a carrier or a designated health care provider terminate their agreement for, or which includes among its terms, the provision of services and supplies to a carrier's covered person for home treatment of bleeding episodes associated with hemophilia, the carrier shall continue to provide services or benefits to or on behalf of a covered person at an in-network level until the end of four months following the date of termination, or until arrangements are made for the covered person to obtain home treatment services and supplies from another in-network designated health care provider, whichever occurs first.

(b) The requirements of (a) above shall not apply when the agreement terminates on the basis of breach, fraud, or a determination by the carrier's medical director that the health care provider is an imminent danger to one or more covered persons, whether such breach, fraud or imminent harm is related to the provision of services or supplies for home treatment of bleeding episodes associated with hemophilia, or other services and supplies for which the carrier and health care provider have an agreement.

1. The carrier shall arrange to pay for services through another designated health care provider.

(c) Nothing in this subchapter shall be construed to limit the statutory or other regulatory obligations that may apply to an agreement between a carrier and a hospital, physician or other health care provider, pursuant to N.J.S.A. 26:2J-11.1 and 26:2S-9.1, for instance, as appropriate to the type of carrier and the type of health care provider.

8:38C-3.6 List of designated home treatment health care providers and State-recognized outpatient regional hemophilia care centers

(a) The Department shall maintain and make available a list of designated health care providers in accordance with N.J.A.C. 8:38C-2.13, and a list of State-recognized outpatient regional hemophilia care centers.

(b) Notwithstanding the Department's maintenance of a list of designated health care providers, nothing in this subchapter shall be construed to limit a carrier's responsibility to assure that a health care provider is designated and remains designated while providing services and supplies to covered persons for the home treatment of bleeding episodes associated with hemophilia.

(c) Nothing in this subchapter shall be construed to limit or eliminate any carrier's obligation to credential and recredential health care providers with which the carrier arranges for the provision of home treatment of hemophilia with respect to such treatments or any other services that the health care provider may render to a carrier's covered persons.

(d) The Department adopts and incorporates herein the standards and procedures used by the Department of Health and Senior Services to designate regional hemophilia treatment centers in accordance with Federal laws.

1. Information regarding the Federally-funded regional hemophilia centers (and grants therefor) may be obtained by contacting the Maternal and Child Health Bureau of the Health Resources and Services Administration within the United States Department of Health and Human Services, or a list of hemophilia treatment centers by state currently is available through the Centers for Disease Control at www.cdc.gov/ncidod/dastlr/hemotology/htc_list.htm.

2. In the event that there is any discrepancy between the Department-generated list of State-recognized outpatient regional hemophilia care centers and the hemophilia treatment centers included in the United States Department of Health and Human Service's regional network(s) for the State of New Jersey, the information provided by the United States Department of Health and Human Services shall take precedence.

8:38C-3.7 Clinical laboratories at State-recognized outpatient regional hemophilia care centers

(a) When a covered person's attending physician determines that a covered person needs to use the services of a clinical laboratory at a State-recognized outpatient regional hemophilia care center because of timing or the need for closely supervised procedures in venipuncture and laboratory techniques, and the carrier does not have an agreement for the provision of services at any clinical laboratory of a State-recognized outpatient regional hemophilia care center, the carrier shall approve the use of such services at the clinical laboratory of a State-recognized outpatient regional hemophilia care center determined appropriate by the attending physician.

1. The carrier shall provide services or benefits to or on behalf of the covered person as if the covered person had accessed services in-network when the services are accessed in accordance with (a)1 above.

2. A refusal by a carrier or its agent to provide benefits or services as if in-network under the circumstances set forth in (a)1 above shall be considered a utilization management denial, and subject to the utilization management appeal process set forth at N.J.A.C. 8:38-8 or N.J.A.C. 8:38A-4.12, as appropriate to the type of carrier.

(b) When a covered person's attending physician determines that a covered person needs to use the services of a clinical laboratory at a State-recognized outpatient regional hemophilia care center because of timing or the need for closely supervised procedures in venipuncture and laboratory techniques, and the carrier has an agreement for the provision of services at a clinical laboratory of one or more State-recognized outpatient regional hemophilia care centers, the carrier may require use of such services at its contracted facitility(ies) in order to obtain in-network benefits or provision of services at the in-network level; however, the carrier shall treat a denial to approve use of the clinical laboratory determined appropriate by the attending physician as a utilization management denial, not an administrative denial, and shall treat any appeal of the denial as a utilization management appeal in accordance with the rules at N.J.A.C. 8:38-8 or N.J.A.C. 8:38A-4.12, as appropriate to the type of carrier.

1. If the covered person is covered under a health benefits plan with out-of-network benefits, the carrier may provide services or benefits to or on behalf of the covered person as if the covered person had accessed services out-of-network.

2. If the covered person is covered under a health benefits plan without out-of-network benefits, the carrier shall pay for the laboratory services at the same rate it would pay

for comparable services at the State-recognized outpatient regional hemophilia care center(s) in the carrier's network.

(c) Nothing in (a) and (b) above shall be construed to otherwise limit a covered person's rights in obtaining services or a carrier's obligations with respect to providing benefits in an emergency.

(d) Treatment by the carrier of a covered person as in-network when accessing the services of a clinical laboratory at a State-recognized outpatient hemophilia care center shall not be contingent upon the status of the attending physician as an in- or out-of-network health care provider with respect to the managed care plan covering the covered person.

(e) Nothing in this subchapter shall be construed to prevent the carrier from reviewing the services provided and making a determination as to whether the services were medically necessary.

8:38C-3.8 Effect of Bulletin OMC 2001-04

(a) Carriers that have agreements for the provision of services and supplies for home treatment of bleeding episodes associated with hemophilia with one or more persons identified in Bulletin OMC 2001-04 as acceptable health care providers of such services may continue to refer covered persons to such health care providers, and the carrier shall be considered in compliance with these rules until whichever occurs first:

1. The 61st day following (the effective date of these proposed new rules), if the health care provider does not submit an application for designation;

2. The Department makes a determination and provides written notice to the person in writing that the person does not meet the standards for designation, if the person files an application for designation in accordance with N.J.A.C. 8:38C-2.4;

3. The person loses designation pursuant to N.J.A.C. 8:38C-2.10; or

4. The carrier and person otherwise terminate their agreement, or amend one or more terms thereof, with respect to the provision of services for home treatment of bleeding episodes associated with hemophilia.

(b) In the event that a person identified in Bulletin OMC 2001-04 as an acceptable health care provider of services and supplies for the home treatment of bleeding episodes associated with hemophilia elects not to file an application for designation, or files an application but does not receive designation, the carrier shall comply with the requirements of N.J.A.C. 8:38C-3.4, as if the person had lost designation.

8:38C-3.9 Identification of hemophilia health care providers by carrier

(a) Carriers shall, within 60 days following (the effective date of these proposed new rules) submit written identification to the Department of the person(s) with which the carrier has an agreement for the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia.

(b) Carriers shall submit the information required in (a) above by mail or by facsimile as follows:

Attn: Hemophilia Health Care Provider Identification

Office of Managed Care

NJ Department of Health and Senior Services

P.O. Box 360

Trenton, NJ 08625-0360

FAX: 609-633-0660

8:38C-3.10 Violations

A carrier that violates any provisions of this subchapter shall be subject to fines and other penalties available pursuant to N.J.S.A. 26:2S-16; however, a carrier shall not be determined to be in violation of the provisions of the subchapter that require contracting with and referral to designated health care providers if there are no designated health care providers in New Jersey on the date that services for the home treatment of bleeding episodes related to hemophilia are sought by or for a covered person.